Pt. 15

Proceedings covered	Statutory authority	Applicable regulations
Proceedings to impose civil monetary penalties, assessments, or exclusions from Medicare and State health care programs. 7. Appeals of exclusions from Medicare and State health care programs and/or other programs.	42 U.S.C. 1395i–3(h)(2)(B)(ii); 1395/(q)(2)(B)(ii); 1395m(a)(11)(A), (c)(4)(C); 1395w–2(b)(2)(A); 1395w–4(g)(1), (g)(3)(B), (g)(4)(B)(ii); 1395nn(g)(5); 1395ss(a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), (t)(2); 1395bbb(f)(2)(A); 1396r(h)(3)(C)(ii); 1396r–8(b)(3)(B), (C)(ii); 1396t(j)(2)(C); 1396u(h)(2). 42 U.S.C. 1395/(q)(2)(B)(ii); 1395m(a)(11)(A), (c)(5)(C); 1395w–	42 CFR part 1003. 42 CFR part 498; 42 CFR 1001.107.
under the Social Security Act.	4(g)(1), (g)(3)(B), (g)(4)(B)(ii).	
Food and Drug Administration		
Proceedings to withdraw approval of new drug applications.	21 U.S.C. 355(e)	21 CFR part 12; 21 CFR 314.200.
 Proceedings to withdraw approval of new animal drug applications and medicated feed applica- tions. 	21 U.S.C. 360b(e), (m)	21 CFR part 12; 21 CFR part 514, Subpart B.
Proceedings to withdraw approval of medical device premarket approval applications.	21 U.S.C. 306e(e), (g)	21 CFR part 12.
Office for Civil Rights		
Proceedings to enforce Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race, color or national origin by recipients of Federal financial assistance.	42 U.S.C. 2000d–1	45 CFR 80.9.
Proceedings to enforce section 504 of the Rehabilitation Act of 1973, which prohibits discrimination on the basis of handicap by recipients of Federal financial assistance.	29 U.S.C. 794a; 42 U.S.C. 2000d–1	45 CFR 84.61.
 Proceedings to enforce the Age Discrimination Act of 1975, which prohibits discrimination on the basis of age by recipients of Federal financial as- sistance. 	42 U.S.C. 6104(a)	45 CFR 91.47.
 Proceedings to enforce Title IX of the Education Amendments of 1972, which prohibits discrimina- tion on the basis of sex in certain education pro- grams by recipients of Federal financial assist- ance. 	20 U.S.C. 1682	45 CFR 86.71.

[69 FR 2847, Jan. 21, 2004]

PART 15—UNIFORM RELOCATION ASSISTANCE AND REAL PROP-ERTY ACQUISITION FOR FEDERAL AND FEDERALLY ASSISTED PRO-GRAMS

AUTHORITY: Sec. 213, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Pub. L. 91-646, 84 Stat. 1894 (42 U.S.C. 4633) as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987, Title IV of Pub. L. 100-17, 101 Stat. 246-256 (42 U.S.C. 4601 note).

§ 15.1 Uniform relocation assistance and real property acquisition.

Regulations and procedures for complying with the Uniform Relocation Assistance and Real Property Acquisi-

tion Policies Act of 1970 (Pub. L. 91–646, 84 Stat. 1894, 42 U.S.C. 4601 et seq.), as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987 (Title IV of Pub. L. 100–17, 101 Stat. 246–256, 42 U.S.C. 4601 note) are set forth in 49 CFR part 24.

 $[52~{\rm FR}~48026,~{\rm Dec.}~17,~1987~{\rm and}~54~{\rm FR}~8912,~{\rm Mar.}~2,~1989]$

PART 16—PROCEDURES OF THE DE-PARTMENTAL GRANT APPEALS BOARD

Sec

- 16.1 What this part does.
- 16.2 Definitions.
- 16.3 When these procedures become available.
- 16.4 Summary of procedures below.
- 16.5 How the Board operates.

- 16.6 Who represents the parties.
- 16.7 The first steps in the appeal process: The notice of appeal and the Board's response.
- 16.8 The next step in the appeal process: Preparation of an appeal file and written argument.
- 16.9 How the Board will promote development of the record.
- 16.10 Using a conference.
- 16.11 Hearing.
- 16.12 The expedited process.
- 16.13 Powers and responsibilities.
- 16.14 How Board review is limited.
- 16.15 Failure to meet deadlines and other requirements.
- 16.16 Parties to the appeal.
- 16.17 Ex parte communications (communications outside the record).
- 16.18 Mediation.
- 16.19 How to calculate deadlines.
- 16.20 How to submit material to the Board.
- 16.21 Record and decisions.
- 16.22 The effect of an appeal.
- 16.23 How long an appeal takes.

Appendix A to Part 16—What Disputes the Board Reviews

AUTHORITY: 5 U.S.C. 301 and secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix.

Source: 46 FR 43817, Aug. 31, 1981, unless otherwise noted.

§ 16.1 What this part does.

This part contains requirements and procedures applicable to certain disputes arising under the HHS programs described in appendix A. This part is designed to provide a fair, impartial, quick and flexible process for appeal from written final decisions. This part supplements the provisions in part 75 of this title.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

§ 16.2 Definitions.

- (a) Board means the Departmental Grant Appeals Board of the Department of Health and Human Services. Reference below to an action of the Board means an action of the Chair, another Board member, or Board staff acting at the direction of a Board member. In certain instances, the provisions restrict action to particular Board personnel, such as the Chair or a Board member assigned to a case.
- (b) Other terms shall have the meaning set forth in part 75 of this title, un-

less the context below otherwise requires.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

§ 16.3 When these procedures become available.

Before the Board will take an appeal, three circumstances must be present:

- (a) The dispute must arise under a program which uses the Board for dispute resolution, and must meet any special conditions established for that program. An explanation is contained in appendix A.
- (b) The appellant must have received a final written decision, and must appeal that decision within 30 days after receiving it. Details of how final decisions are developed and issued, and what must be in them, are contained in 45 CFR 75.374.
- (c) The appellant must have exhausted any preliminary appeal process required by regulation. For example, see 42 CFR part 50 (subpart D) for Public Health Service programs. In such cases, the *final written decision* required for the Board's review is the decision resulting from the preliminary review or appeal process. appendix A contains further details.

[46 FR 43817, Aug. 31, 1981, as amended at 62 FR 38218, July 17, 1997; 81 FR 3012, Jan. 20, 2016]

§ 16.4 Summary of procedures below.

The Board's basic process is review of a written record (which both parties are given ample opportunity to develop), consisting of relevant documents and statements submitted by both parties (see §16.8). In addition, the Board may hold an informal conference (see §16.10). The informal conference primarily involves questioning of the participants by a presiding Board member. Conferences may be conducted by telephone conference call. The written record review also may be supplemented by a hearing involving an opportunity for examining evidence and witnesses, cross-examination, and oral argument (see §16.11). A hearing is more expensive and time-consuming than a determination on the written record alone or with an informal conference. Generally, therefore, the Board will schedule a hearing only if

§ 16.5

the Board determines that there are complex issues or material facts in dispute, or that the Board's review would otherwise be significantly enhanced by a hearing. Where the amount in dispute is \$25,000 or less, there are special expedited procedures (see §16.12 of this part). In all cases, the Board has the flexibility to modify procedures to ensure fairness, to avoid delay, and to accommodate the peculiar needs of a given case. The Board makes maximum feasible use of preliminary informal steps to refine issues and to encourage resolution by the parties. The Board also has the capability to provide mediation services (see §16.18).

§ 16.5 How the Board operates.

- (a) The Board's professional staff consists of a Chair (who is also a Board member) and full- and part-time Board members, all appointed by the Secretary; and a staff of employees and consultants who are attorneys or persons from other relevant disciplines, such as accounting.
- (b) The Chair will assign a Board member to have lead responsibility for each case (the "presiding Board member"). The presiding Board member will conduct the conference or hearing, if one is held. Each decision of the Board is issued by the presiding Board member and two other Board members.
- (c) The Board staff assists the presiding Board member, and may request information from the parties; conduct telephone conference calls to request information, to clarify issues, or to schedule events; and assist in developing decisions and other documents in a case.
- (d) The Chair will assure that no Board or staff member will participate in a case where his or her impartiality could reasonably be questioned.
- (e) The Board's powers and responsibilities are set forth in §16.13.

§ 16.6 Who represents the parties.

The appellant's notice of appeal, or the first subsequent submission to the Board, should specify the name, address and telephone number of the appellant's representative. In its first submission to the Board and the appellant, the respondent (i.e., the federal party to the appeal) should specify the name, address and telephone number of the respondent's representative.

§16.7 The first steps in the appeal process: The notice of appeal and the Board's response.

- (a) As explained in 45 CFR 75.374, a prospective appellant must submit a notice of appeal to the Board within 30 days after receiving the final decision. The notice of appeal must include a copy of the final decision, a statement of the amount in dispute in the appeal, and a brief statement of why the decision is wrong.
- (b) Within ten days after receiving the notice of appeal, the Board will send an acknowledgment, enclose a copy of these procedures, and advise the appellant of the next steps. The Board will also send a copy of the notice of appeal, its attachments, and the Board's acknowledgment to the respondent. If the Board Chair has determined that the appeal does not meet the conditions of §16.3 or if further information is needed to make this determination, the Board will notify the parties at this point.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

§ 16.8 The next step in the appeal process: Preparation of an appeal file and written argument.

Except in expedited cases (generally those of \$25,000 or less; see §16.12 for details), the appellant and the respondent each participate in developing an appeal file for the Board to review. Each also submits written argument in support of its position. The responsibilities of each are as follows:

- (a) The appellant's responsibility. Within 30 days after receiving the acknowledgment of the appeal, the appellant shall submit the following to the Board (with a copy to the respondent):
- (1) An appeal file containing the documents supporting the claim, tabbed and organized chronologically and accompanied by an indexed list identifying each document. The appellant should include only those documents which are important to the Board's decision on the issues in the case.

- (2) A written statement of the appellant's argument concerning why the respondent's final decision is wrong (appellant's brief).
- (b) The respondent's responsibility. Within 30 days after receiving the appellant's submission under paragraph (a) of this section, the respondent shall submit the following to the Board (with a copy to the appellant):
- (1) A supplement to the appeal file containing any additional documents supporting the respondent's position, organized and indexed as indicated under paragraph (a) of this section. The respondent should avoid submitting duplicates of documents submitted by the appellant.
- (2) A written statement (respondent's brief) responding to the appellant's brief.
- (c) The appellant's reply. Within 15 days after receiving the respondent's submission, the appellant may submit a short reply. The appellant should avoid repeating arguments already made.
- (d) Cooperative efforts. Whenever possible, the parties should try to develop a joint appeal file, agree to preparation of the file by one of them, agree to facts to eliminate the need for some documents, or agree that one party will submit documents identified by the other.
- (e) Voluminous documentation. Where submission of all relevant documents would lead to a voluminous appeal file (for example where review of a disputed audit finding of inadequate documentation might involve thousands of receipts), the Board will consult with the parties about how to reduce the size of the file.

§ 16.9 How the Board will promote development of the record.

The Board may, at the time it acknowledges an appeal or at any appropriate later point, request additional documents or information; request briefing on issues in the case; issue orders to show cause why a proposed finding or decision of the Board should not become final; hold preliminary conferences (generally by telephone) to establish schedules and refine issues; and take such other steps as the Board

determines appropriate to develop a prompt, sound decision.

§ 16.10 Using a conference.

- (a) Once the Board has reviewed the appeal file, the Board may, on its own or in response to a party's request, schedule an informal conference. The conference will be conducted by the presiding Board member. The purposes of the conference are to give the parties an opportunity to make an oral presentation and the Board an opportunity to clarify issues and question both parties about matters which the Board may not yet fully understand from the record.
- (b) If the Board has decided to hold a conference, the Board will consult or correspond with the parties to schedule the conference, identify issues, and discuss procedures. The Board will identify the persons who will be allowed to participate, along with the parties' representatives, in the conference. The parties can submit with their briefs under §16.8 a list of persons who might participate with them, indicating how each person is involved in the matter. If the parties wish, they may also suggest questions or areas of inquiry which the Board may wish to pursue with each participant.
- (c) Unless the parties and the Board otherwise agree, the following procedures apply:
- (1) Conferences will be recorded at Department expense. On request, a party will be sent one copy of the transcript. The presiding Board member will insure an orderly transcript by controlling the sequence and identification of speakers.
- (2) Only in exceptional circumstances will documents be received at a conference. Inquiry will focus on material in the appeal file. If a party finds that further documents should be in the record for the conference, the party should supplement the appeal file, submitting a supplementary index and copies of the documents to the Board and the other party not less than ten days prior to the conference.
- (3) Each party's representative may make an oral presentation. Generally, the only oral communications of other participants will consist of statements requested by the Board or responses to

§ 16.11

the Board's questions. The Board will allow reply comment, and may allow short closing statements. On request, the Board may allow the participants to question each other.

(4) There will be no post-conference submissions, unless the Board determines they would be helpful to resolve the case. The Board may require or allow the parties to submit proposed findings and conclusions.

§16.11 Hearing.

- (a) Electing a hearing. If the appellant believes a hearing is appropriate, the appellant should specifically request one at the earliest possible time (in the notice of appeal or with the appeal file). The Board will approve a request (and may schedule a hearing on its own or in response to a later request) if it finds there are complex issues or material facts in dispute the resolution of which would be significantly aided by a hearing, or if the Board determines that its decisionmaking otherwise would be enhanced by oral presentations and arguments in an adversary, evidentiary hearing. The Board will also provide a hearing if otherwise required by law or regulation.
- (b) Preliminary conference before the hearing. The Board generally will hold a prehearing conference (which may be conducted by telephone conference call) to consider any of the following: the possibility of settlement; simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; scheduling the hearing; and any other matter that may aid in resolving the appeal. Normally, this conference will be conducted informally and off the record; however, the Board, after consulting with the parties, may reduce results of the conference to writing in a document which will be made part of the record, or may transcribe proceedings and make the transcript part of the
- (c) Where hearings are held. Hearings generally are held in Washington, DC. In exceptional circumstances, the Board may hold the hearing at an HHS Regional Office or other convenient facility near the appellant.

- (d) Conduct of the hearing. (1) The presiding Board member will conduct the hearing. Hearings will be as informal as reasonably possible, keeping in mind the need to establish an orderly record. The presiding Board member generally will admit evidence unless it is determined to be clearly irrelevant, immaterial or unduly repetitious, so the parties should avoid frequent objections to questions and documents. Both sides may make opening and closing statements, may present witnesses as agreed upon in the prehearing conference, and may cross-examine. Since the parties have ample opportunity to develop a complete appeal file, a party may introduce an exhibit at the hearing only after explaining to the satisfaction of the presiding Board member why the exhibit was not submitted earlier (for example, because the information was not available).
- (2) The Board may request the parties to submit written statements of witnesses to the Board and each other prior to the hearing so that the hearing will primarily be concerned with cross-examination and rebuttal.
- (3) False statements of a witness may be the basis for criminal prosecution under sections 287 and 1001 of Title 18 of the United States Code.
- (4) The hearing will be recorded at Department expense.
- (e) Procedures after the hearing. The Board will send one copy of the transcript to each party as soon as it is received by the Board. At the discretion of the Board, the parties may be required or allowed to submit post-hearing briefs or proposed findings and conclusions (the parties will be informed at the hearing). A party should note any major prejudicial transcript errors in an addendum to its post-hearing brief (or if no brief will be submitted, in a letter submitted within a time limit set by the Board).

§ 16.12 The expedited process.

(a) Applicability. Where the amount in dispute is \$25,000 or less, the Board will use these expedited procedures, unless the Board Chair determines otherwise under paragraph (b) of this section. If the Board and the parties agree, the Board may use these procedures in cases of more than \$25,000.

- (b) Exceptions. If there are unique or unusually complex issues involved, or other exceptional circumstances, the Board may use additional procedures.
- (c) Regular expedited procedures. (1) Within 30 days after receiving the Board's acknowledgment of the appeal (see §16.7), each party shall submit to the Board and the other party any relevant background documents (organized as required under §16.8), with a cover letter (generally not to exceed ten pages) containing any arguments the party wishes to make.
- (2) Promptly after receiving the parties' submissions, the presiding Board member will arrange a telephone conference call to receive the parties' oral comments in response to each other's submissions. After notice to the parties, the Board will record the call. The Board member will advise the parties whether any opportunities for further briefing, submissions or oral presentations will be established. Cooperative efforts will be encouraged (see § 16.8(d)).
- (3) The Board may require the parties to submit proposed findings and conclusions.
- (d) Special expedited procedures where there has already been review. Some HHS components (for example, the Public Health Service) use a board or other relatively independent reviewing authority to conduct a formal preliminary review process which results in a written decision based on a record including documents or statements presented after reasonable notice and opportunity to present such material. In such cases, the following rules apply to appeals of \$25,000 or less instead of those under paragraph (c) of this section:
- (1) Generally, the Board's review will be restricted to whether the decision of the preliminary review authority was clearly erroneous. But if the Board determines that the record is inadequate, or that the procedures under which the record was developed in a given instance were unfair, the Board will not be restricted this way.
- (2) Within 30 days after receiving the Board's acknowledgment of appeal (see §16.7), the parties shall submit the following:
- (i) The appellant shall submit to the Board and the respondent a statement

- why the decision was clearly erroneous. Unless allowed by the Board after consultation with the respondent, the appellant shall not submit further documents.
- (ii) The respondent shall submit to the Board the record in the case. If the respondent has reason to believe that all materials in the record already are in the possession of the appellant, the respondent need only send the appellant a list of the materials submitted to the Board.
- (iii) The respondent may, if it wishes, submit a statement why the decision was not clearly erroneous.
- (3) The Board, in its discretion, may allow or require the parties to present further arguments or information.

§ 16.13 Powers and responsibilities.

In addition to powers specified elsewhere in these procedures, Board members have the power to issue orders (including "show cause" orders); to examine witnesses; to take all steps necessary for the conduct of an orderly hearing; to rule on requests and motions, including motions to dismiss; to grant extensions of time for good reasons; to dismiss for failure to meet deadlines and other requirements: to close or suspend cases which are not ready for review; to order or assist the parties to submit relevant information: to remand a case for further action by the respondent: to waive or modify these procedures in a specific case with notice to the parties; to reconsider a Board decision where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

§ 16.14 How Board review is limited.

The Board shall be bound by all applicable laws and regulations.

§ 16.15 Failure to meet deadlines and other requirements.

(a) Since one of the objectives of administrative dispute resolution is to provide a decision as fast as possible consistent with fairness, the Board will not allow parties to delay the process unduly. The Board may grant extensions of time, but only if the party gives a good reason for the delay.

§ 16.16

(b) If the appellant fails to meet any filing or procedural deadlines, appeal file or brief submission requirements, or other requirements established by the Board, the Board may dismiss the appeal, may issue an order requiring the party to show cause why the appeal should not be dismissed, or may take other action the Board considers appropriate.

(c) If the respondent fails to meet any such requirements, the Board may issue a decision based on the record submitted to that point or take such other measures as the Board considers appropriate.

§ 16.16 Parties to the appeal.

(a) The only parties to the appeal are the appellant and the respondent. If the Board determines that a third person is a real party in interest (for example, where the major impact of an audit disallowance would be on the grantee's contractor, not on the grantee), the Board may allow the third person to present the case on appeal for the appellant or to appear with a party in the case, after consultation with the parties and if the appellant does not object.

(b) The Board may also allow other participation, in the manner and by the deadlines established by the Board, where the Board decides that the intervenor has a clearly identifiable and substantial interest in the outcome of the dispute, that participation would sharpen issues or otherwise be helpful in resolution of the dispute, and that participation would not result in substantial delay.

§ 16.17 Ex parte communications (communications outside the record).

(a) A party shall not communicate with a Board or staff member about matters involved in an appeal without notice to the other party. If such communication occurs, the Board will disclose it to the other party and make it part of the record after the other party has an opportunity to comment. Board members and staff shall not consider any information outside the record (see § 16.21 for what the record consists of) about matters involved in an appeal.

(b) The above does not apply to the following: Communications among

Board members and staff; communications concerning the Board's administrative functions or procedures; requests from the Board to a party for a document (although the material submitted in response also must be given to the other party); and material which the Board includes in the record after notice and an opportunity to comment.

§ 16.18 Mediation.

(a) In cases pending before the Board. If the Board decides that mediation would be useful to resolve a dispute, the Board, in consultation with the parties, may suggest use of mediation techniques and will provide or assist in selecting a mediator. The mediator may take any steps agreed upon by the parties to resolve the dispute or clarify issues. The results of mediation are not binding on the parties unless the parties so agree in writing. The Board will internally insulate the mediator from any Board or staff members assigned to handle the appeal.

(b) In other cases. In any other grants dispute, the Board may, within the limitations of its resources, offer persons trained in mediation skills to aid in resolving the dispute. Mediation services will only be offered at the request, or with the concurrence, of a responsible federal program official in the program under which the dispute arises. The Board will insulate the mediator if any appeal subsequently arises from the dispute.

§ 16.19 How to calculate deadlines.

In counting days, include Saturdays, Sundays, and holidays; but if a due date would fall on a Saturday, Sunday or Federal holiday, then the due date is the next Federal working day.

§ 16.20 How to submit material to the Board.

(a) Submissions should be addressed to the Board's current mailing address: Department of Health and Human Services, Departmental Appeals Board, Appellate Division—MS 6127, 330 Independence Ave. SW., Cohen Building—Rm. G-644, Washington, DC 20201; however, submissions to the Board in certain types of cases may be made by electronic filing using DAB E-File at https://dab.efile.hhs.gov. Changes to the

mailing address will be made available on the Board's Web site at www.hhs.gov/dab/divisions/appellate.

- (b) All submissions after the notice of appeal should identify the Board's docket number (the Board's acknowledgement under §16.7 will specify the docket number).
- (c) Unless the Board otherwise specifies, parties shall submit to the Board an original and two copies of all materials. Each submission other than the notice of appeal, must include a statement that one copy of the materials has been sent to the other party, identifying when and to whom the copy was sent.
- (d) Unless hand delivered, all materials should be sent to the Board and the other party by certified or registered mail, return receipt requested.
- (e) The Board considers material to be submitted on the date when it is postmarked or hand delivered to the Board.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

§ 16.21 Record and decisions.

- (a) Each decision is issued by three Board members (see §16.5(b)), who base their decision on a record consisting of the appeal file; other submissions of parties; transcripts or other the records of any meetings, conferences or hearings conducted by the Board; written statements resulting from conferences; evidence submitted at hearings; and orders and other documents issued by the Board. In addition, the Board may include other materials (such as evidence submitted in another appeal) after the parties are given notice and an opportunity to comment.
- (b) The Board will promptly notify the parties in writing of any disposition of a case and the basis for the disposition.

§ 16.22 The effect of an appeal.

- (a) General. Until the Board disposes of an appeal, the respondent shall take no action to implement the final decision appealed.
 - (b) Exceptions. The respondent may—
- (1) Suspend funding (see §75.371 of this title);

- (2) Defer or disallow other claims questioned for reasons also disputed in the pending appeal;
- (3) In programs listed in appendix A, B.(a)(1), implement a decision to disallow Federal financial participation claimed in expenditures reported on a statement of expenditures, by recovering, withholding or offsetting payments, if the decision is issued before the reported expenditures are included in the calculation of a subsequent grant; or
- (4) Take other action to recover, withhold, or offset funds if specifically authorized by statute or regulation.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

§ 16.23 How long an appeal takes.

The Board has established general goals for its consideration of cases, as follows (measured from the point when the Board receives the first submission after the notice of appeal):

- —For regular review based on a written record under \$16.8, 6 months. When a conference under \$16.10 is held, the goal remains at 6 months, unless a requirement for post-conference briefing in a particular case renders the goal unrealistic.
- —For cases involving a hearing under §16.11, 9 months.
- —For the expedited process under §16.12, 3 months.

These are goals, not rigid requirements. The paramount concern of the Board is to take the time needed to review a record fairly and adequately in order to produce a sound decision. Furthermore, many factors are beyond the Board's direct control, such as unforeseen delays due to the parties' negotiations or requests for extensions, how many cases are filed, and Board resources. On the other hand, the parties may agree to steps which may shorten review by the Board; for example, by waiving the right to submit a brief, by agreeing to shorten submission schedules, or by electing the expedited proc-

APPENDIX A TO PART 16—WHAT DISPUTES THE BOARD REVIEWS

A. What this appendix covers.

This appendix describes programs which use the Board for dispute resolution, the types of disputes covered, and any conditions

Pt. 16, App. A

for Board review of final written decisions resulting from those disputes. Disputes under programs not specified in this appendix may be covered in a program regulation or in a memorandum of understanding between the Board and the head of the appropriate HHS operating component or other agency responsible for administering the program. If in doubt, call the Board. Even though a dispute may be covered here, the Board still may not be able to review it if the limits in paragraph F apply.

B. Mandatory grant programs.

- (a) The Board reviews the following types of final written decisions in disputes arising in HHS programs authorizing the award of mandatory grants:
- (1) Disallowances under Titles I, IV, VI, X, XIV, XVI(AABD), XIX, and XX of the Social Security Act, including penalty disallowances such as those under sections 403(g) and 1903(g) of the Act and fiscal disallowances based on quality control samples.
- (2) Disallowances in mandatory grant programs administered by the Public Health Service, including Title V of the Social Security Act.
- (3) Disallowances in the programs under sections 113 and 132 of the Developmental Disabilities Act.
- (4) Disallowances under Title III of the Older American Act.
- (5) Decisions relating to repayment and withholding under block grant programs as provided in 45 CFR 96.52.
- (6) Decisions relating to repayment and withholding under State Legalization Impact Assistance Grants as provided in 45 CFR 402.24 and 402.25.
- (b) In some of these disputes, there is an option for review by the head of the granting agency prior to appeal to the Board. Where an appellant has requested review by the agency head first, the "final written decision" required by §16.3 for purposes of Board review will generally be the agency head's decision affirming the disallowance. If the agency head declines to review the disallowance or if the appellant withdraws its request for review by the agency head, the original disallowance decision is the "final written decision." In the latter cases, the 30day period for submitting a notice of appeal begins with the date of receipt of the notice declining review or with the date of the withdrawal letter

C. Direct, discretionary project programs.

- (a) The Board reviews the following types of final written decisions in disputes arising in any HHS program authorizing the award of direct, discretionary project grants or cooperative agreements:
- (1) A disallowance or other determination denying payment of an amount claimed under an award, or requiring return or setoff of funds already received. This does not

apply to determinations of award amount or disposition of unobligated balances, or selection in the award document of an option for disposition of program-related income.

- (2) A termination for failure to comply with the terms of an award.
- (3) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.
- (4) A voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).
- (b) Where an HHS component uses a preliminary appeal process (for example, the Public Health Service), the "final written decision" for purposes of Board review is the decision issued as a result of that process.

D. Cost allocation and rate disputes.

The Board reviews final written decisions in disputes which may affect a number of HHS programs because they involve cost allocation plans or rate determinations. These include decisions related to cost allocation plans negotiated with State or local governments and negotiated rates such as indirect cost rates, fringe benefit rates, computer rates, research patient care rates, and other special rates.

E. SSI agreement disputes.

The Board reviews disputes in the Supplemental Security Income (SSI) program arising under agreements for Federal administration of State supplementary payments under section 1616 of the Social Security Act or mandatory minimum supplements under section 212 of Pub. L. 93–66. In these cases, the Board provides an opportunity to be heard and offer evidence at the Secretarial level of review as set out in the applicable agreements. Thus, the "final written decision" for purposes of Board review is that determination appealable to the Secretary under the agreement.

F. Where Board review is not available.

The Board will not review a decision if a hearing under 5 U.S.C. 554 is required by statute, if the basis of the decision is a violation of applicable civil rights or non-discrimination laws or regulations (for example, Title VI of the Civil Rights Act), or if some other hearing process is established pursuant to statute.

G. How the Board determines whether it will review a case.

Under §16.7, the Board Chair determines whether an appeal meets the requirements of this appendix. If the Chair finds that there is some question about this, the Board will request the written opinion of the HHS component which issued the decision. Unless the Chair determines that the opinion is clearly erroneous, the Board will be bound by the

Dept. of Health and Human Services

opinion. If the HHS component does not respond within a time set by the Chair, or cannot determine whether the Board clearly does or does not have jurisdiction, the Board will take the appeal.

 $[46\ FR\ 43817,\ Aug.\ 31,\ 1981,\ as\ amended\ at\ 47\ FR\ 29492,\ July\ 6,\ 1982;\ 53\ FR\ 7864,\ Mar.\ 10,\ 1988;\ 62\ FR\ 38218,\ July\ 17,\ 1997]$

PART 17—RELEASE OF ADVERSE INFORMATION TO NEWS MEDIA

Sec.

- 17.1 Definition.
- 17.2 Basic policy.
- 17.3 Precautions to be taken.
- 17.4 Regulatory investigations and trialtype proceedings.
- 17.5 Context to be reflected.
- 17.6 Advance notice.
- 17.7 Retractions or corrections.

AUTHORITY: 5 U.S.C. 301.

SOURCE: 41 FR 3, Jan. 2, 1976, unless otherwise noted.

§ 17.1 Definition.

Adverse information released by an agency means any statement or release by the Department or any principal operating component made to the news media inviting public attention to an action or a finding by the Department or principal operating component of the Department which may adversely affect persons or organizations identified therein. This part does not apply to nor is it affected by any disclosure of records to the public in response to requests made under the Freedom of Information Act (Pub. L. 90-23). The criteria for such disclosures are set forth in the Department's Public Information Regulation (45 CFR part 5).

§ 17.2 Basic policy.

All adverse information release to news media shall be factual in content and accurate in description. Disparaging terminology not essential to the content and purpose of the publicity shall be avoided.

§17.3 Precautions to be taken.

The issuing organization shall take reasonable precautions to assure that information released is accurate and that its release fulfills an authorized purpose.

§17.4 Regulatory investigations and trial-type proceedings.

Adverse information relating to regulatory investigations of specifically identified persons or organizations or to pending agency trial-type proceedings shall be released only in limited circumstances in accordance with the criteria outlined below:

- (a) Where the Department or a principal operating component determines that there is a significant risk that the public health or safety may be impaired or substantial economic harm may occur unless the public is notified immediately, it may release information to news media as one of the means of notifying the affected public speedily and accurately. However, where the Department or principal operating component determines that public harm can be avoided by immediate discontinuance of an offending practice, a respondent shall be allowed an opportunity, where feasible, to cease the practice (pending a legal test) in lieu of release of adverse information by the agency.
- (b) Where it is required in order to bring notice of pending agency adjudication to persons likely to desire to participate therein or likely to be affected by that or a related adjudication, the Department or principal operating component shall rely on the news media to the extent necessary to provide such notice even though it may be adverse to a respondent.

§ 17.5 Context to be reflected.

The authority for and the character of the information shall be made clear, where appropriate, the release shall explain the nature of any studies performed, the sources of relevant data, the areas in which administrative findings of fact were made, and whether the information is based on allegations subject to subsequent adjudication.

§17.6 Advance notice.

Any respondent or prospective respondent in an agency proceeding shall, if practicable and consistent with the nature of the proceeding, be given advance notice of information to be released about the proceeding and a reasonable opportunity to prepare in